

Appl. No. : 10/776,309
Filed : February 11, 2004

REMARKS

In response to the Office Action mailed April 29, 2010, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. Claims 31, 49, and 99 having been amended, Claims 1-30, 33, 50-98, and 103-123 having been cancelled, and Claims 126 and 127 having been added. Accordingly, Claims 31, 32, 34-49, 99-102, and 124-127 remain pending in the present Application.

The Claim Amendments and Additions are Fully Supported by the Specification

By this paper, Claims 31, 49, and 99 are amended. Applicant hereby submits that these amendments are fully supported by the specification as originally filed.

With regard to Claim 31, Applicant submits that support for the present amendment is found at least at paragraph [0193], which indicates that the basin can include a recessed edge and an inner edge and that “define a contact region 57 that extends between the edges 56a, 56b” and that the contact region is “preferably configured to receive the human anatomy from a point above the hip to a point below the buttock.”

Regarding Claim 49, Applicant submits that support for the present amendment is found at least at paragraphs [0127] and [0128], which indicate that the draining device shown in Figure 3 a “grommet 20,” that the “grommet comprises a sealing part 22,” that the sealing part “comprises a sealing surface 23a” that is “configured to provide a substantially watertight seal with a mating surface (not shown).” Further support is found at least at paragraph [0152], which provides that a convertible portion of the basin is in the form of an “annularly extending score 39 defining a frangible portion disposed on the side surface 38d” and that “[t]he score 39 is configured to form an aperture through the wall 32 or base 11 to drain the cavity 33 following the removal of the material bounded by the score 39 from the wall 32.”

As to Claim 99, support is found at least at paragraph [0002], which states that the “present inventions are directed to surgical equipment, and in particular, equipment used for irrigating wounds on the human body.” Further support is found at paragraph [0224], which indicates that the sheet 71 can define a “variety of shapes” including flat shapes such as a

“circular shape, a square shape, a rectangular shape, a star shape, a diamond shape, and a half-circle shape.”

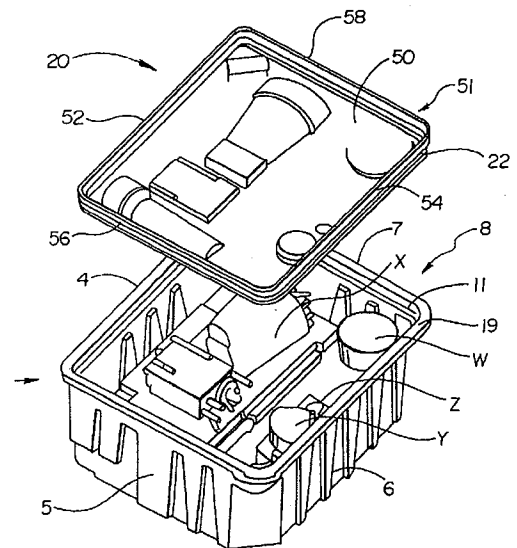
With regard to added Claims 127 and 128, Applicant submits that support is found at least at paragraph [0127], which states that “[t]he grommet can optionally comprise a peel-off seal (not shown)” and “[t]he grommet can optionally comprise a peel-off seal strainer (not shown).”

In light of at least the above, Applicant submits that the amendments and new claims are fully supported by the Specification as originally filed.

The Proposed Combination of Johnson/Smith/Greco Does Not Make Amended Claims 31, 34-48, and 124 Obvious

Claims 31, 34-48, and 124 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,311,838 issued to Johnson *et al.* (“Johnson”) in view of U.S. Patent No. 6,402,724 issued to Smith *et al.* (“Smith”) and further in view of U.S. Patent No. 5,312,385 issued to Greco (“Greco”). Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present application, Applicant has amended independent Claim 31. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraph [0193]. Applicant also expressly reserves the right to further prosecute the original versions of Claim 31 and any claims dependent on it through continuation practice.

Johnson discloses an integrated packaging system for packaging medical components. *See* Figure 1 from Johnson, reproduced at right. The packaging system includes a lid 20 which can be flipped over to convert the packaging system from a shipping mode to a disposal mode, wherein the lid is removable in the shipping mode and non-removable in the disposal mode. *See* Johnson at 7:66-8:37. Angled grooves provide the removable/non-removable functionality. *Id.*



The Office Action asserts: "The different between Johnson and claim 1 is that the kit specifically includes a flexible sheet." Office Action at p. 3. Applicant assumes that the Office Action's recitation of "claim 1" intends Claim 31. The Office Action further asserts that Smith teaches "a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract." *Id.*

Smith teaches a splash shield for use in wound irrigation. The splash shield is made of flexible material "to adapt to the fluid end portion of any number and variety of irrigation fluid delivery devices." Smith, Abstract. See also Figures 1 and 2 from Smith reproduced below.

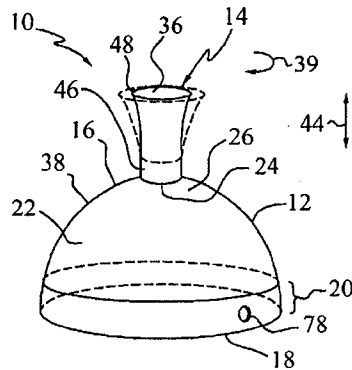


FIG. 1

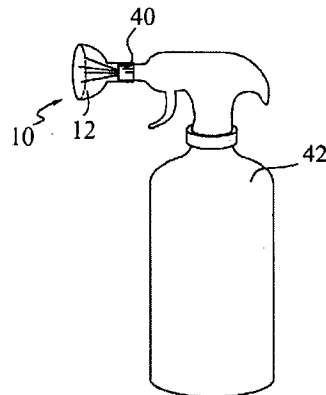
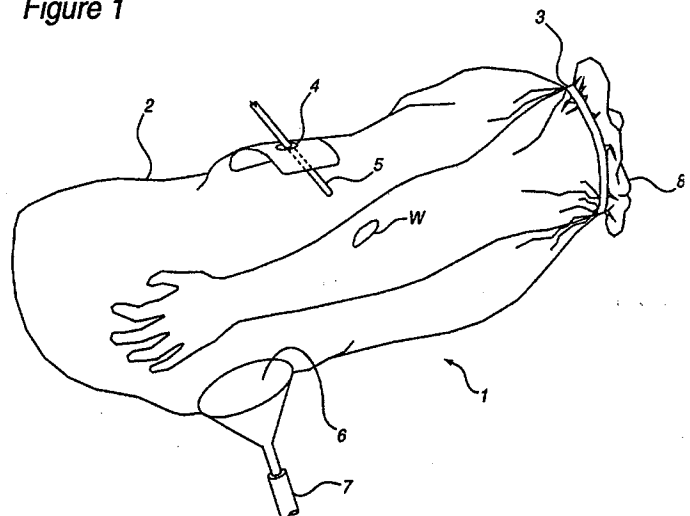


FIG. 2

The Office Action alleges that the difference between Johnson and Smith and Claim 31 is that the "flexible sheet includes a material selected from a specific group" and that "Greco teaches a flexible sheet comprised from material from the claimed group." Office Action at p. 4.

Greco is directed to an enclosure 1 for pulse irrigation. A port 4 receives a tubular irrigation nozzle 5. Spent irrigation fluid flows out an exit port 6. See Figure 1 from Greco, reproduced at right.

Figure 1



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In contrast, amended Claim 31 recites an irrigation kit comprising, *inter alia*, “a basin for collecting irrigation fluid used during a wound irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material, wherein the basin includes a recess for receiving a part of the human anatomy.” Applicant submits that support for this amendment is found at least at paragraph [0193]. Applicant submits that Johnson, Smith, and Greco—alone or in combination—fail to teach or suggest at least the above features of Claim 31.

Johnson does not teach “a basin for collecting irrigation fluid used during a wound irrigation procedure,” per Claim 31. Rather, Johnson teaches a packaging system, such as, for equipment used in heart by-pass surgery. Unless it is the Office Action’s assertion that those skilled in the art would consider **packaging materials** suitable for use as a basin for **medical** procedures, then Johnson cannot teach or suggest such feature. To the extent that the Office Action asserts that those skilled in the art would use packaging materials as a basin in medical procedures, the Office Action should expressly state such a contention and provide support for such a belief.

Even assuming, *arguendo*, that Johnson discloses a basin, the Office Action has not established that Johnson teaches a basin that “includes a recess for receiving a part of the human anatomy,” as recited by Claim 31. Indeed, such a recess would interfere with Johnson’s grooves and/or the angle of the grooves that provides the removable/non-removable functionality. Given that the Office Action has not established that Smith or Greco even teach a basin, Smith or Greco do not remedy the insufficiency of Johnson.

Additionally, Claim 31 recites, among other recitations, “a transparent flexible **sheet** having an aperture configured to engage an irrigation device” and “wherein the aperture, in an enlarged state, is configured to fit over a conical **splash shield** extending distally from a collar attached to a tip of the irrigation device” (emphasis added).

Applicant recognizes that Smith teaches a conical version of a “splash shield”, which is recited in Claim 31. Applicant notes, however, that the Office Action cannot rely on Smith’s conical splash shield as teaching the **combination** of the transparent flexible sheet with an

aperture configured to fit over a conical splash shield.¹ Although the conical splash shield of Smith can be used to teach the recited conical splash shield, it cannot be used to teach the above-noted combination of *two things*. Further, Applicant submits that persons skilled in the art would recognize that it would be impossible to place one of the Smith splash shields over another such splash shield.

This distinction between the flexible sheet and a conical splash shield is important, especially in the area of orthopedic surgery, in which large amounts of irrigation fluid is used. For example, bone fragments, and other contaminants pose a risk to the practitioner in that they can be splashed on to the practitioner during a wound irrigation procedure. *See, e.g.*, paragraphs [0009]-[0011]. Prior art conical splash shields that are fit onto the end of an irrigation device do not provide adequate protection for the practitioner. *See, e.g.*, Figure 2 of Smith shown above. The flexible sheet as described in certain embodiments of the present application provides more surface area for protection.

Applicant thus submits that the combination of Johnson, Smith, and Greco does not render Claims 31 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 31 and pass Claim 31 to allowance. Additionally, Applicant submits that Claims 34-48, and 124 also define over the cited references, not only because they depend from an allowable independent base claim, Claim 31, but also based on their own unique features.

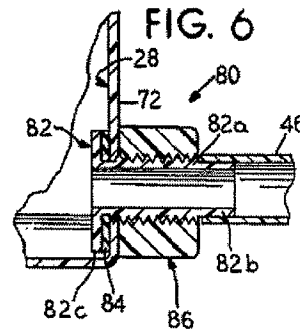
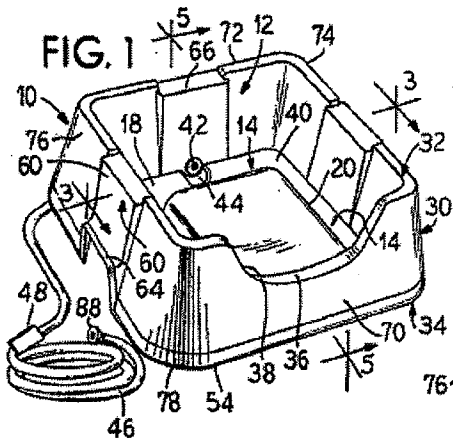
The Proposed Combination of Holloway/Smith Does Not Make Amended Claim 49 Obvious

Independent Claim 49 stands rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,381,562 issued to Holloway *et al.* (“Holloway”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present Application, Applicant has amended Claim 49. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraphs [0127],

¹ Applicant previously presented this argument in the response filed April 15, 2010. The Office Action mailed April 29, 2010 asserts at Page 9 that Applicant’s arguments “have been considered but are moot in view of the new ground(s) of rejection.” Yet the new ground of rejection is based on the addition of Greco (which does not concern conical splash shields) to Johnson and Smith. The new ground of rejection has thus *not* rendered moot Applicant’s argument regarding the inability of Smith to teach the recited *combination*. Accordingly, Applicant’s argument remains unresponded to and is, thus, restated.

[0128], and [0152] and Fig. 3. Applicant reserves the right to further prosecute the original version of Claim 49 through continuation practice.

Holloway discloses a contoured basin. See Figure 1 from Holloway, reproduced below. The basin includes an outlet 42, a hose 46, and a clamp means 48 for "controlling the removal of liquid." Holloway at 7:3-7. The outlet includes an opening in the sidewall of the basin and an adapter 82 threaded to a nut 86 and connected to the hose 46. See Figure 6 from Holloway, reproduced below.



Smith is discussed above.

In contrast, amended Claim 49 recites, *inter alia*, "a basin for collecting irrigation fluid used during a wound irrigation procedure, the basin being sterilized and made of a biocompatible hypoallergenic material" and "a grommet having a sealing surface and configured to connect to a tube to discharge the irrigation fluid."

Amended Claim 49 further states, *inter alia*:

wherein the basin has at least one surface, said surface having at least one convertible portion configured to be convertible between a complete leak proof wall and an aperture configured to allow the basin to be drained through the aperture, wherein the convertible portion includes a scored frangible portion substantially flush with the at least one surface and configured to receive the grommet such that the sealing surface contacts the at least one surface to form a substantially water-tight seal.

Applicant submits that Holloway and Smith, alone or in combination, fail to teach or suggest at least the above features of Claim 49. For example, neither Holloway nor Smith teach

or suggest a convertible portion that includes a “scored frangible portion substantially flush with the at least one surface and configured to receive the grommet such that the sealing surface contacts the at least one surface to form a substantially water-tight seal,” as recited in Claim 49. Rather, Holloway teaches a basin with an opening having a threaded adapter connected to a hose that is clamped to control fluid flow. As such, Holloway’s design allows for multiple points of failure and inadvertent release of liquid. For example, the threaded adapter and/or nut can become loosened and/or stripped thus allowing liquid to pass between the adapter and the basin. Further, the clamp can be inadvertently activated thus allowing liquid to pass through the tube. In contrast, the “scored frangible portion” recited in Claim 49 provides a positive barrier to liquid unless and until a user intentionally activates the frangible portion. Additionally, Claim 49 has the advantage of not needing a separate clamp in order to control the flow of liquid.

Still further, Claim 49 has the advantage of providing a signal (in the form of the activated frangible portion) that the basin has been previously used. Accordingly, a subsequent user can be notified that the basin may no longer be sterile. In comparison, the outlet of Holloway’s basin has no such a signaling configuration.

Additionally, Holloway does not teach or suggest a frangible portion that is “substantially flush” with a surface of the basin. A “substantially flush” closure is advantageous at least because the liquid is maintained within the basin, unlike Holloway in which liquid is allowed into the tube even when the clamp is closed. Applicant notes that U.S. Patent No. 3,407,957 issued to Robinson (“Robinson”)—cited in the Office Action—teaches a frangible closure. But the Office Action has not established that Robinson teaches a frangible closure that is “substantially flush.” Indeed, Robinson’s frangible closures appear to extend beyond the surface to be sealed. *See, e.g.*, Robinson at Figures 1 and 2.

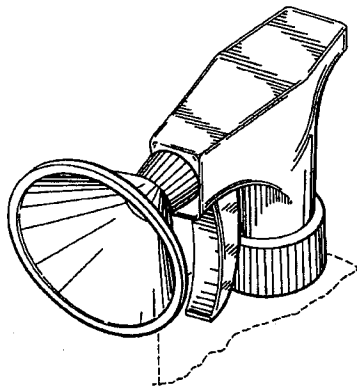
Smith, which is directed toward a splash shield, does not remedy the deficiencies in the teaching of Holloway.

For at least the forgoing reasons, Applicant submits that the combination of Holloway and Smith does not render Claim 49 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 49 and pass Claim 49 to allowance.

The Proposed Combination of Marogil/Smith Does Not Make Amended Claims 99-102 and 125 Obvious

Claims 99-102 and 125 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Design Patent No. 386,684 issued to Marogil (“Marogil”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present Application, Applicant has amended Claim 99. Applicant submits that no new matter has been added and that the amendments are supported in the specification. *See, e.g.*, paragraphs [0002] and [0224] and Figure 12. Applicant reserves the right to further prosecute the original version of Claim 49 through continuation practice.

Marogil teaches an ornamental design for an antiseptic spray nozzle and guard. See Figure 1 of Margil reproduced below. Smith is discussed above.



On page 8 of the Office Action, the Examiner notes that “it would have been obvious... to provide the splash shield of Marogil with the flexible sheet taught by Smith.”

Applicant disputes that the Smith shield is a *sheet*. Rather, the Smith shield is a *conical* splash shield that appears to be nearly identical in shape as the conical splash shield of Marogil. Thus, Applicant submits that one of ordinary skill in the art would not combine one conical splash shield over another conical splash shield.

Nonetheless, assuming, *arguendo*, that the Smith shield is a sheet, the proposed combination would render Marogil unsuitable for its intended purpose. The M.P.E.P makes clear that “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the

proposed modification.” M.P.E.P. § 2143.01 V (citing *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)). Marogil is directed to an antiseptic spray nozzle and guard. Marogil teaches a spray bottle in the vertical position, which is understandable since the vertical position is the standard position in which a spray bottle is used. As shown above in Marogil at Figure 1, Marogil has a guard that extends outward and away from the nozzle and with sufficient rigidity to define a hollow conical space. Thus, when the spray bottle is used the spray can exit from the nozzle and pass through the hollow conical space to a target area. The Office Action proposes adding the alleged flexible sheet of Smith to the spray nozzle of Marogil. However, a flexible sheet would be unable to define the hollow conical space discussed above; the flexible sheet would simply hang downward from the nozzle instead. As such, the sheet would interfere with the path of the spray. Rather than the spray being directed to a target area, the spray would be intercepted by—and leak from—the sheet. Such a result would make Marogil unsuitable for its intended purpose, as well as inoperative. Accordingly, the proposed combination cannot render Claim 99 obvious.

Furthermore, Claim 99 has been amended to recite, *inter alia*, “An irrigation shield for a wound irrigation procedure, the irrigation shield comprising a flat transparent flexible sheet.” Applicant submits that at least these features are not taught or suggested in the cited art.

For at least the forgoing reasons, Applicant submits that the combination of Marogil and Smith does not render Claim 99 obvious. Therefore, Applicant requests that the Examiner withdraw the rejection of Claim 99 and pass Claim 99 to allowance. Additionally, Applicant submits that Claims 100-102 and 125 also define over the cited references, not only because they depend from an allowable independent base claim, Claim 99, but also based on their own unique features.

Dependent Claims 32, 34-48, 100-102, 124, and 125 Depend from Independent Claims 31, 49, or 99

Applicant submits that Claims 32, 34-48, 100-102, 124, and 125 and also define over the cited references, not only because they depend from one of Claims 31, 49, or 99, but also based on of their own unique features.

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New Claims

Applicant hereby submits new Claims 126 and 127 for consideration which are fully supported by the specification as originally filed. *See, e.g.*, paragraph [0127]. Thus no new matter has been introduced. Applicant submits that these claims define over the cited references, not only because they depend from an allowable independent base claim, Claim 49, but also based on their own unique features.

No Disclaimers or Disavowals

Although the present communication may include alterations to the Application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this Application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present Application.

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SUMMARY

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: October 29, 2010

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